

**COMPLETE LISTING OF CLAIMS INCLUDING AMENDMENTS**

1. **(currently amended)** A method for treating a disease by delivering a therapeutic ~~agents~~ agent into the inner ear of a living subject through the round window niche and the round window membrane thereof, ~~for a period of greater than 48 hours~~, said method comprising:

providing a drug delivery unit having a volume of between 0.1 mm<sup>3</sup> and 250 mm<sup>3</sup> wherein the drug delivery unit comprises ~~comprised of~~ at least one biodegradable synthetic controlled release carrier ~~media~~ material adapted for delivery of a therapeutic agent in nanogram to microgram quantities, and at least one therapeutic agent in nanogram to microgram quantities combined therewith, said carrier ~~media~~ material releasing said therapeutic agent from said drug delivery unit over time when said drug delivery unit is placed in said round window niche of said subject; and

placing said drug delivery unit at least partially in said round window niche of said subject; and

allowing said drug delivery unit in said round window niche to release said therapeutic agent therefrom so that said therapeutic agent comes in contact with said round window membrane, passes therethrough, and enters said inner ear, ~~wherein said therapeutic agent is released over a period of greater than 48 hours.~~

2. - 25. **(cancelled)**

26. **(previously added)** The method of claim 1 wherein said drug delivery unit has a length of between about 0.5 mm and 20 mm.

27. **(previously added)** The method of claim 1 wherein said drug delivery unit has a diameter of between about 0.5 mm and 4 mm.

28. **(previously added)** The method of claim 1 wherein said drug delivery unit has a length of between about 0.5 mm and 20 mm and a diameter of between about 0.5 mm and 4 mm.

29. **(currently amended)** The method of claim 1 wherein said therapeutic agent is present in a quantity of between about 10 wt% and 40 wt% of the total weight of the drug delivery unit. ~~to be delivered into said inner ear in microgram or nanogram quantities.~~

30 - 47. **(cancelled)**

48. **(currently amended)** The method of claim 1 wherein the biodegradable synthetic controlled release carrier ~~media~~ material is an injectable material.

49. **(new)** The method of claim 1 wherein said placing of said drug delivery unit is done by injection.

50. **(new)** The method of claim 1 wherein said therapeutic agent is released over at least 24 hours. *new matter*

51. **(new)** The method of claim 1 wherein said therapeutic agent is released over a period of hours.

52. **(new)** The method of claim 1 wherein said therapeutic agent is released over a period of months.

53. **(new)** The method of claim 1 wherein said synthetic controlled release carrier material comprises a polymer.

54. **(new)** The method of claim 1 wherein said synthetic controlled release carrier material comprises a polyanhydride material.

55. **(new)** The method of claim 1 wherein said synthetic controlled release carrier material comprises a polyorthoester material.

56. (new) The method of claim 1 wherein said synthetic controlled release carrier material comprises hydroxypropylmethyl cellulose.

57. (new) The method of claim 1 wherein said synthetic controlled release carrier material comprises hydroxyethyl cellulose.

58. (new) The method of claim 1 wherein said synthetic controlled release carrier material comprises hydrophilic microspheres.

59. (new) The method of claim 1 wherein said synthetic controlled release carrier material comprises a bioadhesive material. *sk*


*g*  
60. (new) The method of claim 1 wherein said drug delivery unit is a multiphased composite drug delivery unit. *sk* (D)

61. (new) The method of claim 1 wherein said drug delivery unit further comprises an impermeable backing membrane, a rate limiting center membrane and a basement membrane comprising a bioadhesive material. *not supported* (D)

62. (new) The method of claim 1 wherein said drug delivery unit comprises a two-layer structure having a hydroxypropyl cellulose bioadhesive layer and a lactose-based non-adhesive baking layer. (D)

63. (new) The method of claim 1 wherein said therapeutic agent is selected from the group consisting of urea, mannitol, sorbitol, glycerol, lidocaine, xylocaine, epinephrine, immunoglobulins, sodium chloride, steroids, heparin, hyaluronidase, aminoglycoside antibiotics, antioxidants, neurotrophins, nerve growth factors, various therapeutic peptides, and polysaccharides.

64. (new) The method of claim 63 wherein said therapeutic agent is an aminoglycoside antibiotic.

 65. (new) The method of claim 64 wherein said aminoglycoside antibiotic is gentamycin.

66. (new) The method of claim 1 wherein said release of said therapeutic agent is achieved by osmosis, diffusion, active/passive transport, or a combination thereof.

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